

### **REMARKS**

In view of the above amendments and arguments submitted herewith, Applicant respectfully submits that the pending application is in condition for allowance.

#### **I. Status of the Claims**

Claims 15, 17, 19-28 and 34-36 are pending. Claims 15, 17, 19, 20 and 25-27 have been amended and new claims 34-36 have been added. Claims 15, 17 and 27 have been amended to specify that the piston has a piston head at one end distal to the needle, that the protective sheath is disposed around the syringe body, that the trigger member is located at the piston head, and that the inhibitor member is configured to be completely removed from the piston or from a remainder of the device while at the inhibit position of the piston. Support for these amendments can be found, for example, on page 8, lines 20-31, page 1, lines 2-15 and page 9, lines 23-26 of the specification, Figs. 1-6 and in the original listing of claims. Claim 19 has been amended to specify that the piston has a piston head at one end distal to the needle, that the protective sheath is disposed around the syringe body, and that the device includes a trigger member positioned at the piston head. Support for these amendments can be found, for example, on page 8, lines 20-31 and page 1, lines 2-15 of the specification, Figs. 1-6 and in the original listing of claims. Claims 20, 25 and 26 have been amended to clarify the claim language. Claim 27 has also been amended to recite that the inhibitor member is received within a slot of the head of the piston. Support for this amendment can be found, for example, on page 8, lines 28-31 of the specification and Figs. 1-5.

New claims 34-36 are each directed to an actuator head of an inhibitor member which is received within a slot of a piston head. Support for these amendments can be found, for example, on page 8, lines 20-33 of the specification and Figs. 1 and 4. No new matter has been added by any claim amendment or new claim.

**II. Rejection Under 35 U.S.C. §103**

1) Claims 15, 17, 32 and 33 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over International Publication No. WO 02/072182 ("Glenord"). The details regarding the rejection of claims 15 and 32 and nearly identical to that of the rejection of claims 17 and 33. As such, Applicant has combined the response to the rejection of claims 15, 17, 32 and 33 for purposes of brevity.

The Examiner asserts that Glenord discloses that the inhibitor member 23, 36, 37 is formed by a tenon or by a wall element on the outside of the piston head, but concedes that Glenord does not disclose that the inhibitor member passes through the head of the piston. However, the Examiner contends that it would have been obvious to one skilled in the art to modify the Glenord device such that the inhibitor member was moved from the outside of the head of the piston, to be placed on the inside of the head of the piston, as it has been held that mere reversal of essential working parts of a device involves only routine skill in the art. (Office Action, page 4, lines 11-18 and page 6, line 20 through page 7, line 5). The feature of a longitudinal portion formed by a tenon or a wall element of the inhibit member that passes through the head of the piston via a slot has been canceled from claims 15 and 17, thus rendering the rejection as to this issue moot.

With respect to amended independent claims 15 and 17, without explicitly stating so, the Examiner contends that Glenord discloses each and every element of the claims. In particular, the Examiner asserts that Glenord discloses a syringe having a trigger member 30 secured to (i.e., connected to) an actuator head of a piston, as shown in Fig. 1. Furthermore, the Examiner contends that the inhibitor member 36 may be moved out of the way of completion of the injection stroke and that the inhibitor member is suitable for being separated or displaced from the piston to enable the second end-of-injection strike position to be reached. That is, the inhibitor member 36 is moved from the inhibit position (Fig. 1) to a separated or displaced position (Fig. 3), such that the trigger member 30 can activate the device to its protection

configuration, as best shown in Fig. 5. (Office Action page 3, lines 3-5 and 9-22 and page 5, line 12 through page 6, line 9). Applicant respectfully traverses this rejection in view of the foregoing amendments.

In the instant invention, as shown in Fig. 1 of the specification, the syringe device includes a piston 12 having a rear piston head 12B. The rear piston head 12B is configured with a trigger member 30 that is connected thereto and which is positioned at the location of the piston head 12B. Additionally, the syringe device includes a completely removable inhibitor member 34 assembled to the piston head 12B through slots 36 formed within the piston head 12B. The inhibitor member 34 also includes an actuator head 39 to allow a user to advance the piston 12 distally.

Thus, the present invention contrasts distinctly from the device of Glenord for the following reasons. First, the asserted trigger member 30 of Glenord, as best shown in Fig. 3, is not connected to the head of the piston 22, but instead connected to a mid-portion of the piston 22 spaced apart from the piston head 34. Thus, Glenord does not disclose a trigger member that is “located at the piston head” or “secured to the piston at the piston head,” as presently recited in amended claims 15 and 17, respectively.

Second, the asserted inhibitor member 23, 36, 37 of Glenord is not completely removable from the piston 22, but instead pivoted from one position to another as shown in Figs. 1-3. See also page 5, line 24 through page 6, line 6 of Glenord. Thus, Glenord does not disclose an inhibitor member “configured for being completely removed from the piston at said inhibit position of the piston” or “configured for being removed from a remainder of the device while at said inhibit position,” as presently recited in amended claims 15 and 17, respectively.

Claims 32 and 33 were previously cancelled in response to the prior July 21, 2009 Office Action. Accordingly, reconsideration and withdrawal of the rejection of claims 15 and 17 are respectfully requested.

2) Claims 19-28 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Glenord. The details regarding the rejection of independent claim 19 are similar to those for independent claim 27. As such, Applicant has combined the response to the rejection of claims 19 and 27 for purposes of brevity.

Similar to the rejection of claims 15 and 17, the Examiner asserts an obvious contention with respect to the feature of an inhibitor member passing through the head of a piston for claims 19 and 27. The features of a longitudinal portion formed by a tenon or a wall element of the inhibit member that passes through the head of the piston via a slot has been canceled from claims 19 and 27, thus rendering the rejection as to this issue moot.

With respect to independent claims 19 and 27, without explicitly stating so, the Examiner contends that Glenord discloses each and every element of the claims. In particular, the Examiner asserts that Glenord discloses a syringe having a trigger member suitable for causing the device to pass from the injection configuration to the protection configuration at the end of the injection stroke. (Office Action, page 7, lines 18-20 and page 11, lines 1-2). Additionally, with respect to claim 27, the Examiner further asserts that the trigger member is formed by a skirt secured to the piston head 30. (Office Action, page 11, lines 3-4). Applicant respectfully traverses this rejection.

Independent claim 19 has been amended to recite, *inter alia*, as follows:

A safe injection device comprising  
a syringe having a syringe body, a needle, and a piston  
suitable for moving in the body to perform an injection, the piston  
having a piston head at one end distal to the needle, and  
...  
a trigger member positioned at the piston head for causing the  
device to pass from the injection configuration to the protection  
configuration at the end of the injection stroke, ... (emphasis added).

Independent claim 27 has been amended to recite, *inter alia*, as follows:

A safe injection device comprising

a syringe having a syringe body, a needle, and a piston suitable for moving in the body to perform an injection, the piston having a head that includes a slot, and

...

a trigger member suitable for causing the device to pass from the injection configuration to the protection configuration at the end of the injection stroke, the trigger member being formed by a skirt secured to the piston at the piston head,

an inhibitor member formed by a part that, in an inhibit position, is removably fitted on the head of the piston and received within the slot of the head of the piston and presents an end suitable for coming into abutment against an element that is stationary relative to the syringe body in order to define a first end-of-injection-stroke position for the piston in which the skirt is unable to cause the device to pass from the injection configuration to the protection configuration ... (emphasis added).

As discussed above with respect to the rejections of independent claims 15 and 17, Glenord fails to disclose a trigger member located at a piston head of a piston. That is, Glenord merely discloses an asserted trigger member 30, as best shown in Fig. 3, that is connected to a mid-portion of the piston 22 spaced apart from the piston head 34. Thus, Glenord does not disclose or suggest a “trigger member positioned at the piston head” or a “trigger member being formed by a skirt secured to the piston at the piston head,” as presently recited in amended claims 19 and 27, respectively.

Furthermore, claim 27 recites a “piston having a head that includes a slot” and an “an inhibitor member ... removably fitted on the head of the piston and received within the slot of the head of the piston....” However, Applicant can find no disclosure whatsoever regarding a piston head slot configured for receiving an inhibit member in the device of Glenord.

Therefore, for the foregoing reasons, Applicant respectfully submits that Glenord fails to render obvious independent claims 19 and 27. Further, claims 20-26 and 28 each depend from either claim 19 or 27. As such, claims 20-26 and 28 should be allowable based at least upon

their dependency from their respective base claims. Accordingly, reconsideration and withdrawal of the rejection of claims 19-28 are respectfully requested.

### **III. New claims**

New claims 34-36 have been added and Applicant respectfully requests consideration and allowance of these claims. Claims 34-36 each depend from either independent claim 15, 17 or 19 and thus should be allowable based at least upon their dependency from their respective base claims. Furthermore, claims 34-36 are each directed to an actuator head of an inhibitor member which is received within a slot of a piston head. Fig. 1 best illustrates the actuator head 39 of the inhibitor member 34 received within a slot 36 of the piston head 12B of the instant invention. The actuator head 39 allows a user to advance the piston distally when received within the slot 36 of the piston head 12B.

In contrast however, the device of Glenord does not disclose both a piston head and an actuator head. That is, the syringe 10 only includes a single piston head (e.g., see reference numeral 34) fixed to the piston 22 to allow a user to advance the piston 22 distally. Plus, the piston head 34 of Glenord does not include a slot for receiving therethrough the inhibitor member 23, 36, 37. As shown in Fig. 3 of Glenord, the asserted inhibitor member 23, 36, 37 is merely connected to a distal end of the piston head 34.

Moreover, as asserted in the rejection of claims 15, 17 and 19, it appears that the Examiner agrees the Glenord does not disclose an inhibitor member that passes through the head of a piston. However, it also appears that the Examiner is contending that such a feature of an inhibitor member passing through the head of a piston would have been obvious. Specifically, the Examiner asserts that it would have been obvious to modify Glenord such that the inhibitor member was moved from the outside of the head of the piston head to the inside of the head of the piston, as it is merely a reversal of an essential working part.

Applicant respectfully submits that it would not have been obvious to move the inhibitor member 23, 36, 37 to the inside of the piston head 34, as contended by the Examiner. The piston head 34 is merely a flat planar member, as shown in Fig. 1 of Glenord. As such, Applicant cannot imagine how the inhibitor member 23, 36, 37 would be moved to the inside of the piston head 34. Furthermore, merely forming the inhibitor member 23, 36, 37 on the inside of the piston head 34 would result in a configuration in which the inhibitor member 23, 36, 37 is received within a slot of the piston head 34, as such a proposed modification of the Glenord device would not result in a piston head having a slot.

Even assuming *arguendo*, that it would have been obvious to modify Glenord to move the inhibitor member 23,36,37 to the inside of the piston head 34, it still would not result in the claimed invention of claims 34-36. That is, as discussed above, the modified Glenord device still would not disclose both a piston head and an actuator head, or a piston head having a slot. Therefore, Applicant respectfully submits that claims 34-36 contain subject matter that is patentable over the prior art of record.

### **Conclusion**

Insofar as the Examiner's rejections were fully addressed, Applicants respectfully submit that the instant application including claims 15, 17, 19-28 and 34-36, is in condition for allowance. Issuance of a Notice of Allowability of all pending claims is therefore earnestly solicited.

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Respectfully submitted,

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(Date)

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